DEC 23 2004

510(k) SUMMARY

This summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Trade Name:	**TANITA InnerScan Body Composition Monitor Models BC-533, BC-534 and BC-550**
Common Name:	**Body Composition Analyzer / Body Fat Analyzer / Body Fat Monitor**
Classification Name:	**ANALYZER, BODY COMPOSITION 21 CFR § 870.2770**

Description of Applicant Device:
The TANITA InnerScan Body Composition Monitor is a computer-operated body composition analyzer that utilizes BIA (bioelectrical impedance analysis) to determine body fat percent, body water percent, muscle mass, bone mass, visceral fat rating, metabolic age, physique rating and daily calorie intake.

	Model Number		
Body Composition Capabilities	*BC-533*	*BC-534*	*BC-550*
Total Body Water % (TBW %)	✓	✓	✓
Visceral Fat Rating	✓		
Bone Mass	✓	✓	✓
Muscle Mass / Physique Rating	✓		
Daily Calorie Intake (DCI) / Metabolic Age	✓	✓	
Daily Calorie Intake (DCI)			✓

Intended Uses of Applicant Device:
Intended to be used as a body fat analyzer that determines body weight and estimates body fat with the use of BIA (bioelectrical impedance analysis). Other outputs include total body water, DCI (daily calorie intake), bone mass, visceral fat rating, metabolic age, physique rating and muscle mass.

Predicate Devices:
TANITA Body Fat Analyzer Professional and Consumer Models
K014009

510(k) SUMMARY, continued

This summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Scientific Concepts and Significant Performance Characteristics:

	Tanita Body Composition Analyzer Professional Models K014009	Tanita Body Composition Analyzer Consumer Models K014009	Tanita InnerScan Body Composition Monitor Models BC-533, BC-534 & BC-550
INTENDED USE:	A combination non-invasive device, which determines weight and estimates body fat and total body water using BIA (bioelectrical impedance analysis).	A combination non-invasive device, which determines weight and estimates body fat using BIA (bioelectrical impedance analysis).	A combination non-invasive device, which determines weight and estimates total body fat, visceral fat rating, bone mass, total body water, muscle mass, metabolic age, physique rating and daily calorie intake with the use of BIA (bioelectrical impedance analysis).
PRODUCT DESCRIPTION:	Body composition analyzer/scale that utilizes a "foot-to-foot" BIA (bioelectrical impedance) technology to determine internal body composition.	Body composition analyzer/scale that utilizes a "foot-to-foot" BIA (bioelectrical impedance) technology to determine internal body composition.	Body composition monitor/scale that utilizes a "foot-to-foot" BIA (bioelectrical impedance) technology to determine internal body composition.
ANALYTICAL METHOD/ MEASUREMENT	▪ Foot-to-Foot BIA ▪ In-house BIA and DEXA reference methods	▪ Foot-to-Foot BIA ▪ In-house BIA and DEXA reference methods	▪ Foot-to-Foot BIA ▪ In-house BIA, DEXA, Deuterium Dilution and MRI reference methods

Side by side comparison of the TANITA InnerScan Body Composition Monitor to the predicate devices clearly demonstrates that the applicant device is substantially equivalent to the legally marketed devices.

Based on the results of using the previously approved "Foot-to-Foot" BIA methodology with our patented in-house BIA, it was concluded that the TANITA InnerScan Body Composition Monitor performs as well as the predicate devices and therefore have proven its safety and efficacy.

Rhoda Lynn Valera, RAC
TANITA Corporation of America
Regulatory Affairs Specialist

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Arlington Heights, IL 60005
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Fax: (847) 640-7978

December 20, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2004

Ms. Rhoda Lynn N. Valera
Regulatory Affairs Specialist
TANITA Corporation of America, Inc.
2625 South Clearbrook Drive
ARLINGTON HEIGHTS IL 60005

Re: K040778
Trade/Device Name: TANITA InnerScan Body Composition Monitor
BC-533, BC-534 and BC-550
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: 74 MNW
Dated: November 10, 2004
Received: November 12, 2004

Dear Ms. Valera:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K040778

Device Name: TANITA InnerScan BC-533, BC-534 and BC-550 Body Composition Monitor

Indications for Use: The TANITA family of InnerScan Body Composition Monitors measure body weight and impedance and estimate percentage of body fat and body water, visceral fat rating, bone mass, muscle mass, physique rating, daily calorie intake (DCI) and metabolic age using BIA (bioelectrical impedance analysis). They are intended for use by healthy children 7-17 years old and healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment.

	Model Number		
Body Composition Capabilities	*BC-533*	*BC-534*	*BC-550*
Total Body Water % (TBW %)	✓	✓	✓
Visceral Fat Rating	✓		
Bone Mass	✓	✓	✓
Muscle Mass / Physique Rating	✓		
Daily Calorie Intake (DCI) / Metabolic Age	✓	✓	
Daily Calorie Intake (DCI)			✓

Prescription Use_____ AND/OR Over-the-Counter Use____✓_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyngaas

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040778